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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/004,587  | 12/04/2001  | Michael A. Tainsky   | 0788.00063          | 5172             |
| 7590  | 12/29/2005  |                      | EXAMINER            |                  |
| Kenneth I. Kohn<br>Kohn & Associates<br>Suite 410<br>30500 Northwestern Highway<br>Farmington Hills, MI 48334 |             |                      | CLOW, LORI A        |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1631                |                  |
| DATE MAILED: 12/29/2005   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/004,587             | TAINSKY ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Lori A. Clow, Ph.D.    | 1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 October 2005.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 and 10-19 is/are pending in the application.
  - 4a) Of the above claim(s) 1-6 and 10-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 7 and 8 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 May 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 18 October 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8 and 10-19 are currently pending. Claim 9 has been cancelled. Claims 7 and 8 are hereby examined, as they are drawn to the elected invention.

Claim1-6 and 10-19 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 26 April 2004.

**Drawings**

The drawings submitted 23 May 2003 are accepted.

**Specification**

The use of the trademarks BLAST and GenBank have been noted in this application, for example (page 58, line14). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that there may be other instances of trademarks in the specification and that this is merely an example.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites “differentially biopanning sera obtained from a normal individual and patients with the disease against phage display libraries expressing cDNA of genes expressed by diseased cells to obtain epitope-bearing clones displaying reactivity to antibodies present in sera of patients with disease but not in sera of normal individuals to array for analysis”. It is unclear what is intended by this limitation. Does Applicant intend that the epitope-bearing clones be

subjected to the array for analysis or that the clones themselves are arrayed or is there some other meaning? Clarification is requested.

Claim 8 recites “the method according to claim 7, wherein said determining step includes using a computer”. There is insufficient antecedent basis in the claim for “determining”, as no step of determining is present in claim 7. It is unclear where this step is to be implemented. What part of the “biopanning” step is determined using a computer? Clarification is requested.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Sioud et al.

(European Journal of Immunology (2001) Vol. 31, pages 716-725).

The instant claims are drawn to a method of detecting a combination of markers indicative of disease stage by differentially biopanning sera from normal and diseased patients and identifying epitope bearing clones present in the disease stage, thereby detecting markers of disease.

In regard to claim 7, Sioud teaches the analysis of the humoral response in patients with cancer. Libraries from breast cancer cell lines were biopanned and positive clones were selected. Using serum antibodies from patients with breast cancer, IgG-binding phage-encoded cDNA products were selected and the clones identified important antigens including p53, pentraxin and

others. The selected phage-displayed cDNA products were recognized by a significant number of breast cancer sera as compared to normal individuals (abstract; Results and Discussion section 2.2 on page 717).

In regard to claim 8, a computer is utilized to quantitate densitometric imaging on an immunospot assay that was used to determine the presence or absence of antibodies against the selected phage-encoded cDNA products in normal and cancer patient sera. Thus, “analyzing” results of the biopanning step (page 718, column 1, paragraph 1).

Sioud anticipates all of the limitations of instant claims 7 and 8.

### **Conclusion**

In view of Applicants amendments to claim 7, the outstanding enablement rejection and the outstanding new matter rejection under 35 USC 112, 1<sup>st</sup> paragraph and have been withdrawn. Thus, Applicants arguments with regard to such are moot.

In view of Applicant amendments to claims 7 and 8 the outstanding rejections under 35 USC 112, 2<sup>nd</sup> paragraph have been withdrawn. As such, Applicant arguments are moot.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 21, 2005

Lori A. Clow, Ph.D.

Art Unit 1631

*Lori A. Clow*  
Patent Examiner